

## SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS (SACATM) FIVE-YEAR PLAN WORKING GROUP

### Background

Congress established the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to promote development, validation, and regulatory acceptance of new or revised alternative toxicological test methods that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness (42 U.S.C. 2851-3). The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) was established to administer ICCVAM and provide scientific and operational support for the committee. Congress requested that NICEATM and ICCVAM, in partnership with relevant federal agencies, develop a five-year plan that addresses the following two objectives: (1) research, development, translation, and validation of new and revised non-animal and other alternative assays for integration into federal agency testing programs and (2) identification of areas of high priority for new and revised non-animal and alternative assays for replacement, reduction, and refinement (less pain and distress) of animal tests.

Development of the draft five-year plan is a multi-step process. NICEATM and ICCVAM solicited information for consideration in developing the plan from interested stakeholders via the Federal Register (71FR66172) and NTP and ICCVAM electronic listserv notices. At the meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on November 30, 2006, the committee provided NICEATM and ICCVAM input to consider in developing the plan, and this meeting also provided an opportunity for public comment. NICEATM and ICCVAM provided the comments from SACATM and the public to the 15 ICCVAM agencies and requested information from them for use in developing the draft plan. ICCVAM created a Five-Year Plan Subcommittee to draft a five-year plan that ICCVAM has considered and endorsed. The draft plan will be available for public comment beginning May 7, 2007 and a town meeting is planned for June 11 (72FR23832). The National Institute of Environmental Health Sciences (NIEHS), NICEATM, and ICCVAM seek comments from SACATM on the draft five-year plan that NICEATM and ICCVAM can consider before finalizing the plan. SACATM will discuss the draft five-year plan at its meeting on June 12.

SACATM is a federally chartered advisory committee whose members are appointed by the Director, NIEHS and NTP. SACATM provides primary scientific oversight on the statutorily mandated duties of ICCVAM and the activities of NICEATM.

### Purpose

The Five-Year Plan Working Group (FYPWG) is established as an *ad hoc*, scientific, advisory body to provide SACATM advice and comments on the draft five-year plan and how well it addresses the two objectives identified above. The FYPWG shall present its report to SACATM at the June 12 meeting.

### Structure

The FYPWG's membership shall be sufficiently broad to promote input and exchange of ideas and information. The FYPWG shall consist of five members, including the Chair, with broad representation including industry, animal welfare, academia, and development of alternative

methods. The chair shall be a member of SACATM appointed in consultation with the SACATM chair. The FYPWG shall report to SACATM.

The NTP Liaison and Scientific Review Office (LSRO) within the Office of the NTP Associate Director shall provide support services for the FYPWG. LSRO will work with NICEATM to provide the FYPWG information about the draft plan and its process for preparation and to coordinate interactions with ICCVAM.

#### **Meetings**

The FYPWG is anticipated to meet from May through June 2007 in-person or by conference call and present its findings to SACATM at the June 12 meeting, although the working group's tenure may be extended if SACATM perceives a need. A government official shall be present at all meetings. The FYPWG will follow appropriate National Institutes of Health (NIH) guidelines for the management, oversight, and conduct of working groups.

#### **Compensation**

FYPWG members shall be paid at a daily rate equivalent to that of SACATM members, plus per diem and travel expenses. Members who are officers or employees of the U.S. government shall not receive compensation for service.

#### **Termination**

The NWG shall continue until deemed no longer necessary by SACATM with approval by the government official.